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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,550	11/24/2003	Ulrich Walter Drees	9/269	4564

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,550	DREES ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted June 25, 2007 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferry et al. (US 6,147,095 IDS), in view of Loutfy et al.

3. Ferry et al. teaches a method for improving the pharmacokinetics of tipranavir comprising administering a combination of therapeutical effective amount of tipranavir, and a therapeutical effective amount of ritonavir. See the claims. The method is particular useful for treatment of diseases caused by HIV, such as AIDS. See, particularly, col. 6, line 1 to col. 7, line 3.

4. Ferry et al. do not teach expressly the treatment of "highly treatment experienced" HIV-infected patients, or the further incorporation of other anti-HIV drugs, capravirine, and/or "optimized background regimen comprising at least one nucleoside reverse transcriptase inhibitor." (see page 4 of the specification).

5. However, Ferry et al. reveals that it is well known in the art that to use combination of different types of antiviral drugs (cocktail) for treatment of HIV-infections. Currently three types of antiretroviral drugs are commonly used: nucleoside reverse transcriptase inhibitors (NRTI);

non-nucleoside reverse transcriptase inhibitors (NNRTI), and protease inhibitors (PI). See, particularly, col. 2, line 63 to col. 3, line 35. Further, Loutfy et al. disclosed that it is a common practice in the art of HIV-infection treatment to use new developed antiretroviral drugs for those patients who fails to response to known cocktail treatments. See, particularly, pages 81, page 84, the right column. Loutfy et al. also disclosed that tipranavir (PI) and capravirine (NNRTI) are two of the new antiretroviral drugs. See, page 86, particularly table 2. Loutfy et al. further disclosed that the employment of genotyping and phenotyping for optimization of a cocktail anti-HIV regimen is known in the art. See, page 85.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the combination of tipranavir and ritonavir disclosed by Ferry for treatment of those HIV-infected patients who fails to response effectively to other combination therapy, particularly in combination with other new antiretroviral drugs, such as capravirine to form a new cocktail regimen, because new drug is generally effective against those strain resistant to current drugs. Note Tipranavir is particularly known for that (see page 86 in Loutfy). Further, optimization of the drug cocktail based on genotyping and/or phenotyping would have been obvious to one of ordinary skill in the art since such technique is known in the art. Incorporation of another different type of drug (NRTI) would have been obvious to one of ordinary skill in the art because it is known in the art to use different types of drugs in a cocktail combination.

Response to the Arguments

Applicants' amendments and remarks submitted June 25, 2007 have been fully considered, but are not persuasive.

6. Appellants' remarks as to "obvious to try" is not convincing, particularly, in view of KSR vs. Teleflex, where the court states:

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.** In that instance the fact that a combination was obvious to try might show it was obvious under section 103." In the instant case, each and every ingredients herein are known anti-HIV agents but with different antiviral mechanisms. In view of the fact that combination of different drug with different mechanisms will yield better efficacy against the viral infection, a knowledge available to the artisan, one of rodinary skill in the art would have reasonably anticipated the success of the combination of them for the same purpose.

The evidence of record shows that the subject matter as claimed is a combination of known components selected for their known properties as anti-viral agents, and known synergistic effects when combined with the other. A claim which unites elements with no change in their respective functions to yield a predictable result is not patentable.

For over a half century, the [Supreme] Court has held that a "patent for a combination which only unites old elements with no change in their respective functions ...obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152 [87 USPQ 303] (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR Int'l v. Teleflex Inc., 82 USPQ2d 1385, 1395 (2007).

No explicit teaching is necessary to have led the skilled worker to the particular components – combination for three known antiviral agents - recited in claims because each was known in the prior art to be effective against HIV and are particularly useful when combined with other antiviral agents with different mechanisms.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617